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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/520,085

04/18/2005

Thierry Massfelder

BJS-3665-133

9193

23117 7590 02/23/2009
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EXAMINER

GUSSOW, ANNE

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

02/23/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/520,085	Applicant(s) MASSFELDER ET AL.	
	Examiner ANNE M. GUSSOW	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-20,23-26,31 and 33-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-20,23-26,31 and 33-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/27/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claim 17 has been amended.
Claims 1-16, 21-22, 27-30, 32, and 36-52 have been cancelled.
2. Claims 17-20, 23-26, 31, and 33-35 are under examination.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on December 1, 2008 was filed after the mailing date of the first action on the merits on March 6, 2008. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner and an initialed copy of the IDS is included with the mailing of this Office Action.

Rejections Withdrawn

4. The rejection of claims 17-20, 23-26, 31, and 33-35 under 35 U.S.C. 112, second paragraph as being indefinite is withdrawn in view of applicant's amendment to the claims.

Rejections Maintained

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. The rejection of claims 17-20, 23-26, 31, and 33-35 under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement is maintained.

Applicant's response and Abdelghani declaration filed November 27, 2008 have been carefully considered by the examiner but are deemed not to be persuasive. The response states that the specification describes several antagonists including, peptides of PTH or PTHrP (response page 10), a non-peptidic compound (response page 11), and a compound, such as an anti-PTHrP antibody (response page 12). The response further states that the present disclosure describes the claimed invention and uses a commercially available product to exemplify the disclosed and claimed invention and that the examiner's use of *In re Smith* is misplaced (see response pages 4-17). The Abdelghani declaration duplicates applicant's remarks (see declaration pages 5-10).

In response to this argument, the specification contemplates compounds other than the claimed antibodies as antagonists of PTHrP, however, the claims define the antagonist as an anti-PTHrP antibody that binds within amino acids 34-53 of PTHrP, and the antibody described in the specification relating to treating kidney cancer is the anti-PTHrP(34-53) Ab2 available from Oncogene (currently available from Calbiochem EMD). The broad disclosure, i.e., anti-PTHrP antibodies and a single species, i.e., the anti-PTHrP(34-53) Ab2 available from Oncogene does not provide adequate written description for the currently claimed subgenus of anti-PTHrP antibodies that bind residues 34-53.

On page 1 of the specification the amino terminal (N-term) is defined as 1-36, the intermediate region as 38-94/95/101, and the carboxy terminal (C-term) as 107-139, however, in the examples the antibodies used for the amino terminal is 1-34, the intermediate is 36-53, and the carboxy terminal is 107-139 (pages 26-27). The definition of the intermediate region, i.e., residues 38-94/95/101 and a single antibody that happens to bind to residues 34-53 would not have led the skilled artisan to the currently claimed subgenus of anti-PTHrP antibodies that bind within residues 34-53. Neither the region of amino acids 34-53 nor antibodies thereto are clearly disclosed.

While one would understand that the antibody from Oncogene binds to an epitope within residues 36-53, there is no disclosure of residues 34-53, except provided in the name of the Oncogene antibody. The written description does not contemplate or disclose the subgenus of antibodies that bind within amino acids 34-53.

The examiner's use of *In re Smith* is not misplaced, as *In re Smith* is cited to show that a generic disclosure and a species upon which it reads does not provide adequate written description for the subgenus. Applicant is reminded that it cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See *In re Smith* 173 USPQ 679, 683 (CCPA 1972) and MPEP 2163.05. Similarly, applicants' broad disclosure of anti-PTHrP antibodies and the disclosure of the single species anti-PTHrP(34-53) Ab2 available from Oncogene, which happens to bind within residues 34-53 as implied by the nomenclature, does not provide adequate written description for the currently claimed subgenus of anti-PTHrP antibodies that bind within residues 34-53. Also see, *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) (subgenus range was not supported by generic disclosure and

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specific example within the subgenus range). In re Smith is cited in the MPEP regarding determining sufficient written description to inform a skilled artisan that applicant was in possession of the claimed invention as a whole at the time the application was filed (MPEP 2163,3,(a) and MPEP 2163,3,(b)).

Thus, in view of the evidence of record and the inconsistency in the specification regarding the regions of the PTHrP protein, applicant has not shown possession of a genus of anti-PTHrP antibodies that bind amino acids 34-53 of the claimed therapeutic method.

Therefore after a fresh consideration of the claims and the evidence provided the rejection is maintained.

Conclusion

7. No claims are allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNE M. GUSSOW whose telephone number is (571)272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow

February 11, 2009

/David J Blanchard/
Primary Examiner, Art Unit 1643